UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

PLAINTIFFS' SUR-REPLY IN OPPOSITION TO DEY'S MOTION FOR PARTIAL SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

In its reply, Dey admits that by 1999 it was "readily apparent" that there existed "'spreads' of at least 99 percent between the AWP and WAC for each of [its] Subject Drugs." (Dey Reply Br. at 1.) This admission confirms Plaintiffs' allegation that Dey reported grossly inflated AWPs to the compendia—that its AWPs were false under the California False Claims Act (CA FCA). Despite this, Dey argues that because California had throughout the relevant period known of the inflated nature of AWP, Plaintiffs cannot establish that Dey had the requisite scienter under the CA FCA, and that its motion for partial summary judgment should be granted. For the reasons stated below, however, Defendant's "government knowledge" argument fails as a matter of law. Its motion should therefore be denied.

First, while Dey argues that its pricing notification letters, comparisons of its WAC prices to its AWPs, the OIG reports, and the DOJ AWPs collectively should have enabled California to discern Dey's pricing fraud, it presents no evidence that California was in fact aware, on a drug-by-drug basis, of Dey's real prices, or the full extent of the spreads between the providers' actual cost of acquisition and the AWPs Dey reported for its Subject Drugs. Furthermore, nothing in the record indicates that Medi-Cal ever knowingly approved of or acquiesced to Dey's fraudulent AWPs. Accordingly, Dey has failed to establish, as it must, that Medi-Cal knew the true and actual nature of Defendant's grossly inflated AWPs, and that it mandated, approved of, or decided as a matter of policy to acquiesce to Dey's practice of reporting fraudulent AWPs. *See In Re Pharm. Indus. Average Wholesale Price Litig. ("New York")*, No. 01-12257, at 25 (D. Mass. Jan. 27, 2010) (order granting and denying motions for summary judgment) (docket no. 6863).

In this regard, it is important to bear in mind that Dey never fully informed California of the fact or magnitude of its grossly inflated AWPs. Moreover, there is no evidence that, during the relevant period, Dey acted in good faith pursuant to the explicit direction of an appropriate policy statement issued by Medi-Cal that might excuse Dey's failure to report AWPs in accordance with California law. Rather, Dey's defense is premised almost entirely on third-party information (such as OIG reports and the DOJ AWPs), which Dey contends Medi-Cal could and should have pieced together to discern the true nature of their fraud. But this post hoc rationalization for its failure to report accurate AWPs (as it was required to do under California law) comes nowhere close to the kind of scienter-defeating, "government knowledge" defense courts have traditionally recognized in the context of false claims litigation.

Dey further maintains that California's failure to change its Medi-Cal pharmacy reimbursement system in response to manufacturers' practice of reporting inflated AWPs should be seen by the Court as approval or acquiescence of that practice. This argument, however, is neither supported by law, nor is it consistent with common sense. It has always been the case that, to the extent a manufacturer like Dey chooses to participate in California's Medicaid program, it is required to follow the applicable law and regulations set forth by the State. The State is not required to rewrite its laws and regulations simply because Dey or other manufacturers choose to violate them. And in any event, as this Court has held, evidence of government knowledge concerning an issue "does not support an across-the-board government knowledge defense [where] there is no evidence of government sanction." *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 151 (D. Mass. 2008). The evidence that Dey relies on is devoid of anything amounting to such sanction of Dey's conduct; at most, that evidence shows that the State failed to promptly adjust its reimbursement system to deal with Dey's misconduct.

This is no defense. Government lethargy "does not translate into approval." *Id.* This conclusion is particularly apt in the context of this action, where Medi-Cal's complex reimbursement system was embodied in a regulation that governed the conduct of hundreds of drug companies, by which many, unlike Dey, abided without incident.

Recognizing that it cannot show government approval of its conduct, Dey retreats to a second, equally baseless, argument—namely, that the governing law and regulations were unclear, and that it did not know it was required to report AWPs that reasonably estimated the providers' actual costs to acquire its drug products. Dey's claims to the contrary notwithstanding, the evidence clearly shows that it deliberately gamed Medi-Cal's drug reimbursement system in order to market its products. While Plaintiffs need not prove Dey's motive, the evidence of its reasons for falsely reporting its AWPs is manifest.

Finally, as a matter of law, Dey's claimed "good faith" misunderstanding of the pricing term "AWP" is not a defense. By participating in the Medicaid system, Dey was charged with educating itself as to the system's requirements. To the extent Dey had a good faith question about its legal obligations to California with respect to its pricing practices, or the meaning of terms such as AWP, Dey was required to seek clarification from appropriate government officials. But, of course, it never sought such clarification, most likely because it was never Dey's intention to accurately report the AWPs for its Subject Drugs in any event. Its government knowledge defense, therefore, is simply without merit.

ARGUMENT

I. THE GOVERNMENT KNOWLEDGE DEFENSE UNDER THE CA FCA REQUIRES GOVERNMENT SANCTION, NOT MERE INACTION.

The government knowledge defense requires government sanction of a party's conduct, not simply government inaction when on notice of a party's failure to comply with regulatory requirements. That is very clear from the controlling California cases construing the CA FCA.

As Plaintiffs have previously noted, the three reported California cases recognizing the government knowledge defense all involved situations where the responsible government officials affirmatively approved the underlying conduct with full knowledge of the relevant facts. *See People v. Duz-Mor Diagnostic Lab., Inc.*, 68 Cal. App. 4th 654, 672 (1998) (finding no violation where "Duz-Mor adopted the billing practice at issue here on the instructions of a Medi-Cal representative, and did not knowingly make a false claim"); *Laraway v. Sutro & Co.*, 96 Cal. App. 4th 266, 277 n.4 (2002) (holding that "there can be no false claim where a contractor has submitted a claim in accordance with government directions, even if the procedure was improper"); *American Contract Services v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 865 (2002) ("*ACS*") (holding that there was no CA FCA claim where the alleged wrongdoing "was known to and initiated by the government").

Dey argues that "[n]one of the cases California cites . . . hold that there must be some direct communication of approval between the government and the defendant." (Dey Reply Br. at 3.) That argument, however, simply ignores the fact that the Court of Appeal in *ACS*, *supra*, expressly held that where "the government knows *and approves of* the particulars of a claim for payment before the claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim. In such a case, the government's knowledge effectively negates the fraud or falsity required by the CA FCA." *Id.* at 864, *quoting U.S. ex rel. Durcholz v. FKW, Inc.*,

189 F.3d 542, 544-45 (7th Cir. 1999). The *ACS* Court cited *Duz-Mor*, *supra*, for the principle that there was "no False Claims Act violation where the contractor had done only *what was directed by government officials.*" *ACS, supra*, 94 Cal. App. 4th at 864-65 (emphasis added). It is hard to imagine much clearer language. In short, under controlling California law the government knowledge defense to a CA FCA claim requires government approval. Dey's inability to point to any evidence of such approval dooms its argument.

A. Dey's Federal Case Citations Do Not Support Its Position.

The federal cases Dey cites do not construe the CA FCA, and, in any event, do not support Dey's argument. As noted above, in *ACS*, the California Court of Appeal adopted the reasoning of the Seventh Circuit's oft-cited decision in *Durcholz.* While not controlling here, *Durcholz* and the great weight of cases construing the federal FCA require government approval to make out a viable "government knowledge" defense.

As this Court and others have previously held, a state's failure to abandon a reimbursement system "does not equate to government knowledge or approval." *See, e.g.*, *Mylan Labs.*, 608 F. Supp. 2d at 152; *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d. 277, 285 (D. Mass. 2006) ("The weight of the legislative history reflects congressional intent to have the AWP moored to actual wholesale pricing, and a nagging concern that AWP was no longer a reasonable price"); *In re Lupron Sales Practices*, 295 F. Supp. 2d 148, 168 n.19 (D. Mass. 2003) ("recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct"); *see also, United States v. Michael Schiavone & Sons, Inc.*, 430 F.2d 231, 233 (1st Cir. 1970) ("[e]ven if there had been some evidence of governmental acquiescence in the 1960 sale, that would not bar the government from bringing this suit, for it is not true that once a

government agency smells a rat, the agency must exterminate it forthwith or allow it the run of the public's house *in perpetuo*").

Indeed, even the authorities that Dey relies on simply do not support its position given the circumstances here. For instance, Dey's reliance on *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931 (10th Cir. 2008) is unavailing. The *Orenduff* decision unambiguously describes the "government knowledge inference" as applicable only "when the government *knows and approves of the facts underlying an allegedly false claim prior to presentment*. *Id*. at 952 (emphasis added). Even Dey's quotation from that decision makes clear that a key predicate for the government knowledge inference is the "degree to which the government invites that claim." *Id.* at 954. In *Orenduff*, the court found that the Department of Education's inclusion of NMSU on a list of minority institutions, after NMSU had been "completely forthcoming" with the agency, constituted government authorization for the school to apply for the contracts at issue. *Id.* Here, by contrast, Dey was hardly forthcoming about the fact that its AWPs had enormous spreads over average acquisition costs, and Medi-Cal never authorized the submission of AWPs with such spreads. To the contrary, the plain language of the term AWP, as well as its use in the regulation as a means to estimate providers' acquisition costs, made clear that companies were required to report AWPs that reasonably related to such acquisition costs. *Orenduff* supports Plaintiffs' position; not Dey's.[1]

Dey's reliance on *United States ex rel. Englund v. Los Angeles County*, 2006 WL 3097941 (E.D. Cal. Oct. 31, 2006), an FCA action based on Los Angeles County's alleged

[1] Judge Jones' concurring opinion in *United States v. Southland Mgmt. Corp.*, 326 F.3d 669 (5th Cir. 2003), as referenced by Dey, is inapposite. Judge Jones initially concluded that the allegedly false certifications at issue were not material to HUD's decision to pay Defendants' claims. *Id*. at 679-81. She further concluded that the evidence demonstrated that Defendants had not acted with scienter and that HUD's decision to pay the claims was based "not on its ignorance of the [project's] true condition but upon the imperative to provide housing for the tenants while HUD supervised the use of the limited funds it allocated to the project." *Id.* at 683-84. There is no comparable evidence here.

improper use of Medicaid funding, is also misplaced. There, the court found that "officials on both the State and Federal levels were well aware of the County's actions and understood the alleged 'scheme' to be legal." *Id*. at *13. According to the court, this *shared understanding* that the conduct was that which legally negated the County's scienter. *Id*. Indeed the use of the intergovernmental transfers at issue was apparently authorized by Congress, which expressly granted California relief from restrictions placed on other states. *Id*. Dey overreaches in analogizing the complex, *negotiated* arrangements between State, County, and Federal officials at issue in *Englund* to its wholly unauthorized practice of reporting grossly inflated AWPs at issue in this case.

II. DEY'S PROFFERED EVIDENCE FAILS TO SUPPORT ITS GOVERNEMENT KNOWLEDGE DEFENSE.

Dey is silent with regard to the period from 1994 to 1999, apparently conceding thereby that it has no defense before 1999. Puzzlingly, Dey has selected January 1999 as the date California supposedly had knowledge of Dey's fraudulently inflated prices, but it is unclear where that particular date comes from. Dey does not point to any particular piece of evidence dated January 1999; rather, it appears to be an arbitrary date. But in any event, from 1999 on, in addition to the absence of any evidence of government approval, the evidence that Dey relies upon fails to make out a government knowledge defense. First, Dey has not shown that it provided Medi-Cal with all of the relevant facts regarding its reporting of inflated AWPs. Second, the evidence that Dey relies upon does not undercut California's evidence that Dey knowingly caused the submission of false claims. As the Second Circuit has noted, "the statutory basis for an FCA claim is the defendant's knowledge of the falsity of its claim, which is not automatically exonerated by any overlapping knowledge [of] government officials." *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1156 (2d Cir.), *cert.*

denied, 508 U.S. 973 (1993). Third, Dey has provided no evidence that it at all relied on California's purported knowledge or understanding as to Dey's interpretation of the term AWP when Dey reported its inflated prices. In reality, the evidence that Dey relies upon simply confirms that it acted *with* scienter.

Dey's argument that it did not understand that it was supposed to report AWPs that reasonably reflected providers' acquisition costs is untenable in light of the regulatory language and the plain meaning of the term. When Dey chose to participate in Medi-Cal, it undertook the duty to familiarize itself with the legal requirements of the program. *See, e.g.*, *Heckler v. Community Health Services of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984); *North Mem'l Med. Ctr. v. Gomez*, 59 F.3d 735, 739 (8th Cir. 1995), including the procedures and legal requirements applicable to reimbursements. *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001). Dey chose to have Medi-Cal reimburse for its drugs, and, as a matter of law, it was consequently charged with the knowledge of the relevant statutes and regulations. Dey was therefore required to know that California's definition of Estimated Acquisition Cost ("EAC"), of which AWP was a reference component, "means the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package." CAL. WELF. & INST. CODE § 14105.45(a)(4) (West 2004).

A. Dey's Few Price Notification Letters Were Merely Marketing Materials that Hardly Qualify as Full and Complete Disclosures of the Falsity of its AWPs.

Beginning in March 1999, Dey sent eleven "price notification" letters over a three-year period to various state Medicaid agencies, but can offer only five letters that were specifically sent to California. Dey argues these five letters expressly notified California that Dey's AWP

was not a price actually charged or paid for Dey's drugs. (Dey SOF ¶¶ 33, 35.[2]) Nothing could be farther from the truth. Either individually or together, the gist of these letters gave no indication that Dey was offering important information about its AWPs. More importantly, none of them come close to fully and properly notifying the appropriate Medi-Cal personnel that Dey had long been reporting grossly inflated AWPs contrary to California law, and that it intended to continue doing so.

Of these five letters, three of them appear to be largely marketing tools. Respectively, they begin: "Dear Administrator: Dey is pleased to introduce EasiVent™ Mask for use with EasiVent Valved Holding Chamber…" (March 16, 1999, Reid Decl. Ex. 29); "Dear Administrator: We have introduced a new Albuterol Inhalation Aerosol, 17g Metered Dose Inhaler Kit and Refill from Dey…" (July 18, 2000, Reid Decl. Ex 32); "ATTENTION: State Medicaid Administrator: Effective immediately, Dey has introduced a private label Astech® Peak Flow Meter manufactured exclusively for CVS®/pharmacy." (August 2, 2000, Reid Decl. Ex. 34.) A fourth letter announces Dey's new sterile albuterol sulfate: "Dear Administrator: During the week of July 26, 1999, Dey introduced a new sterile-produced Albuterol Sulfate Inhalation Solution 0.5% multidose concentrate, replacing the current 0.5% solution." (August 10, 1999, Reid Decl. Ex 30.) By all appearances, these letters were mass-mailed advertisements for new product launches; not important and legally meaningful declarations intended to inform appropriate personnel at Medi-Cal that Dey's AWPs were grossly inflated beyond any reasonable estimation of their cost of acquisition by providers. Tellingly, nothing in the subject line of any of these letters indicates Dey's disavowal of the accuracy of its AWPs, that it is seeking clarification concerning its obligations under California law with regard to price

[2] Statement of Undisputed Materials Facts in Support of Dey's Motion for Partial Summary Judgment (hereinafter "Dey SOF") (docket no. 6695).

reporting, or that it is requesting approval of its grossly inflated AWPs. The alleged disclaimer is hardly a conspicuous aspect of any of the letters, and none of the letters are addressed to an official authorized to make any decisions on behalf of California with respect to Dey's obligation to report AWPs in accordance with California law.

In addition, while Plaintiffs' entire case is confined exclusively to generic drugs, only three of these letters—Dey's Exhibits 30, 32, and 35—concern generic drugs. Moreover, Dey's Exhibit 30 mentions only two NDCs, explaining that a new NDC is replacing the old one. Dey's Exhibit 32, a letter sent July 18, 2000, lists 14 new AWPs. The last paragraph provides that Dey does not change its AWPs, but then says it is changing its AWPs.[3] So while Dey is relying on a short history of letters described as intending to notify California that it does not change its AWPs, this disclaimer appears in a letter changing its AWPs. (Reid Decl. Ex 32)

Exhibit 35 is a letter sent January 2001 and is the only letter which appears to have as its primary purpose the notification of WAC and AWP price changes. This letter contains 10 generic NDCs and lists a column of new WAC prices and a column labeled NEW AWP. However, written in the AWP column for each of the 10 drugs are the words "No change." So while the last paragraph indicates that Dey has chosen to change the AWP on these products, there are no AWP prices for these drugs, even though Dey says there are.

Finally, this Court has recently held that Dey's WAC prices on certain forms of albuterol, a drug with NDCs common to California's case,[4] were inflated and false as a matter of law, ostensibly during the same time period as that at issue in this case. *New York*, No. 01-12257, at

[3] "Generally, it is DEY's practice to set an AWP before a product is first sold and not to subsequently change that AWP. We understand that this is consistent with industry practice. We believe this to be clearly understood by state and federal Medicaid regulators. DEY has chosen to change the AWP on these products at this time principally due to current conditions in the marketplace." (Reid Decl. Ex 32.)

[4] Albuterol 90 mcg inhaler and albuterol .83 mg solution, 9 NDCs in California's case.

2, n.2, and 18. Consequently Dey's arguments concerning the purported import of their WAC prices, with respect to notifying California about the falsity of Dey's AWPs, is wholly bankrupt.

In summary, Dey's price notification letters appear to be little more than marketing materials, as opposed to legitimate and comprehensive disclosures to Medi-Cal concerning Dey's unlawful pricing practices with respect to the Subject Drugs. The self-serving, inconspicuous, boilerplate disclaimers these letters included were hardly sufficient to inform California that Dey's AWPs were grossly inflated beyond any reasonable relationship to the providers' actual cost of acquisition. Moreover, they failed to reveal Dey's real prices for the Subject Drugs, as required to under California law, or the enormous spreads between provider acquisition cost and AWP. Finally, the record is bereft of any evidence that California, in response to Dey's disclaimers, approved or ratified Dey's fraudulent pricing practices, or that Dey ever sought clarification from California about what its AWPs were intended to reflect under the applicable law.

Not surprisingly, Dey argues that this Court, in *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127 (D. Mass. 2008), held that general and oblique disclosures of information, such as those relied upon by Dey in the instant case, are sufficient to make out a government knowledge defense. As *Mylan Labs.* makes clear, however, and as this Court has most recently confirmed in *New York*, substantially more is required. In *Mylan Labs.*, this Court methodically cited several prior false claims cases[5] from various courts around the country in which the government knowledge defense was considered. *Mylan Labs.*, 608 F. Supp. 2d at 148. The clear import of this Court's analysis of these cases in *Mylan Labs.* is that the government knowledge defense is

[5] Specifically, the Court cited *United States ex rel. Durcholz v. FKW Inc*., 189 F. 3d 542, 545 (7th Cir. 1999); *Shaw v. AAA Eng'g & Drafting, Inc*., 213 F. 3d 519, 534 (10th Cir. 2000); *United States ex rel. Becker v. Westinghouse Savannah River Co*., 305 F.3d 284, 289 (4th Cir. 2002); and *United States ex rel. Butler v. Hughes Helicopters, Inc*., 71 F.3d 321, 327 (9th Cir. 1995). *See Mylan Labs.*, 608 F. Supp. 2d at 148.

properly asserted only where the government possesses "actual true facts of the claim, not simply knowledge that the claim is generally false," and "the government approves of the false claim." *Id*. In other words, "[t]o prevail on a government knowledge defense, Defendants must produce admissible evidence that [the government] or its agencies knew that actual true facts, and that they ordered, asked for, approved or decided as a policy matter to acquiesce in the Defendants' reporting of false prices." *New York*, No. 01-12257, at 25, citing *Mylan Labs.*, 608 F. Supp. 2d at 148-52. Only where the "defendant and the government 'so completely cooperated and shared all information'" can one conclude that defendant's claims "could not be knowingly false." *Mylan Labs.*, 608 F. Supp. 2d at 149, citing *United States ex rel. Butler v. Hughes Helicopters, Inc*., 71 F.3d 321, 327 (9th Cir. 1995).

As indicated above, by no means has Dey demonstrated that California had the actual true facts concerning Dey's false pricing-reporting practices, or that it in any way "ordered, asked for, approved or decided as a policy matter to acquiesce in the [Dey's] reporting of false prices." *New York*, No. 01-12257, at 25. For this reason alone, Dey's Motion must be denied.

B. Medi-Cal Had No Obligation to Consider Dey's WACs.

California had no obligation to examine Dey's reported WAC prices and compare them to its AWPs, and the evidence does not support the conclusion that California did so. Dey contends that California had ready access to WAC prices; however, in the context of Medi-Cal's reimbursement system, this is not the case. Because California had to pay for the data files it used for reimbursement purposes, (Hanscom Sur-Reply Decl. Ex. 25 at 114:22-115:21[6]), and because WAC prices had no relevance to the Medi-Cal program, California did not typically obtain WAC prices from First DataBank. (*Id.* at 104:2-4) Accordingly, California did not

[6] Declaration of Rita Hanscom in Support of Sur-Reply in Opposition to Dey's Motion for Partial Summary Judgment ("Hanscom Sur-Reply Decl.").

typically have access to its WAC prices, either through the computer system utilized to effect reimbursement (*Id.* at 104:2-20), or through RAIS, its system designed to track rebates. (*Id.* at 98:22-99:4, 103:21-104:1.) Medi-Cal simply did not track or maintain any WAC pricing information for any purpose. (*Id.* at 104:2-4.) As of its contract ending July 1, 2002, DHCS paid First DataBank $15,000 per month for one customized file containing the specific pricing information DHCS wanted. (*Id.* at 114:22-115:21, 116:4-7.) The data in the customized file did not include WAC prices. (*Id.* at 104:10-20; 115:9-20.) Although staff pharmacist Vic Walker testified in his May 21, 2009, deposition that DHCS was "currently getting" WAC prices from First DataBank (Hanscom Sur-Reply Decl. Ex. 26 at 77:3-9), Walker subsequently clarified that the pricing data to which he had been referring was not WAC but "WHN"—wholesale net prices:

> A. . . . I should say that the field that's on the First DataBank file that we used is called WHN, net wholesale, and that's the value that we used. [¶] I don't think there's a field on the – First DataBank NDDF national drug data file that's in – that's titled "WAC."
>
> Q. So First DataBank provided you with what it called "WHN prices"?
>
> A. Yeah. Yeah.
>
> Q. And that's a title that First DataBank gave those prices?
>
> A. Yes, which means "net wholesale."

(Hanscom Sur-Reply Decl. Ex. 26 at 88:3-15.)

In addition, although Dey contends that Chief of Medi-Cal Pharmacy Policy Kevin Gorospe testified that Medi-Cal considered using WAC prices in 2004, Plaintiffs' alleged damages period only runs until the end of 2004. The State's generalized awareness by that date that WAC may have been a more accurate pricing metric than AWP does not in any way negate

Dey's scienter with regard to reporting grossly inflated AWPs. Again, California did not have an understanding of the actual, true facts concerning the AWPs for Dey's Subject Drugs, and, in any event, California never approved or acquiesced to Dey's reporting of grossly inflated AWPs. More to the point, because California has never reimbursed on the basis of WAC, it never had any reason to examine the true relationship between WAC prices and AWPs. As Dey's own counsel elicited from Dr. Gorospe:

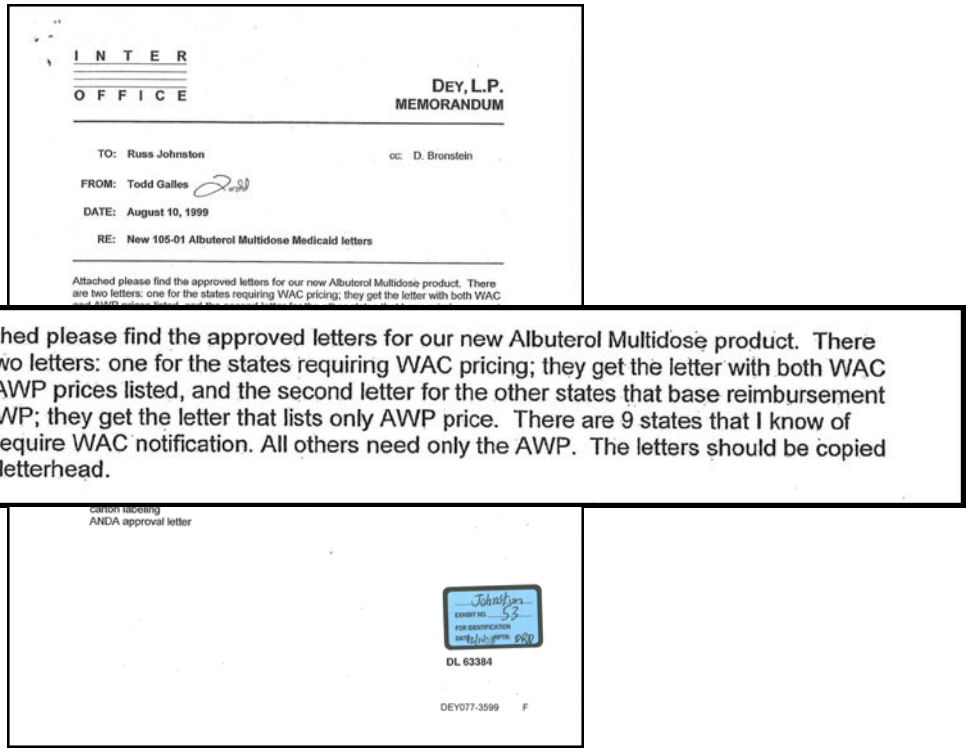
> Q. . . . Now, WAC has no bearing on the -- on the California Medicaid reimbursement; does it?
>
> A. No, it does not.
>
> Q. And it plays no part in your work with Medicaid program?
>
> A. No, it does not.
>
> Q. And it didn't at the time of this letter?
>
> A. No, it did not.
>
> Q. Okay. So whatever Dey said about WAC wouldn't have affected you -- you or your job in Medi-Cal one way or the other; would it?
>
> A. No, it would not.

(Hanscom Sur-Reply Decl. Ex. 27 at 687:9-21.)

Dey's insistence that California should have compared its WAC prices with its AWPs is both ironic and misleading, inasmuch as none the five previously referenced price notification letters Dey sent to California included *both* WAC and AWP prices for Dey's generic drugs. While Dey may have sent certain States price information that showed both WACs and AWPs for its products, the information that it sent California only showed AWPs.[7]

[7]While Exhibit 30 appears to contain both WAC and AWP for one NDC, it is not the letter California was sent. Perhaps due to error or oversight, Dey has failed to produce the correct pricing notification letter. There are two, nearly identical pricing notification letters dated August 10, 1999, but Dey has provided only one of them in Exhibit

Perhaps understandably, Dey has also omitted the August 10, 1999 memo attached to these two letters. Written by Todd Galles, Dey's Senior Product Manager, this memo clearly reveals an intent to conceal the differential between WAC prices and AWP. Galles writes:



INTER OFFICE

DEY, L.P. MEMORANDUM

TO: Russ Johnston cc: D. Bronstein

FROM: Todd Galles

DATE: August 10, 1999

RE: New 105-01 Albuterol Multidose Medicaid letters

Attached please find the approved letters for our new Albuterol Multidose product. There are two letters: one for the states requiring WAC pricing; they get the letter with both WAC and AWP prices listed, and the second letter for the other states that base reimbursement off AWP; they get the letter that lists only AWP price. There are 9 states that I know of that require WAC notification. All others need only the AWP. The letters should be copied onto letterhead.

carton labeling
ANDA approval letter

Johnston EXHIBIT NO. 53 FOR IDENTIFICATION DATE 1/20/10 KPR

DL 63384

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(*See* Hanscom Sur-Reply Decl. Ex. 28.) Clearly, despite its claims, Dey had no intention of facilitating California's comparison of AWPs to WAC prices.

In addition, even assuming California paid any attention to WAC prices, which it was not obligated to do, given Dey's apparent refusal to accurately publish its AWPs, there is nothing to suggest that Dey's WAC prices were any more reliable than its AWPs. Numerous WAC states, such as Massachusetts, Florida, and Texas, have pursued drug-pricing litigation based on Dey's WACs. And if that were not enough, as early as 1995, Dey itself observed that its WAC

30. (Reid Decl. Ex 30). The letter Dey has failed to produce is identical except that it shows AWP only. (Reid Decl. Ex 30).

prices were not necessarily "real" prices: "WAC is not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement." (*See* Hanscom Sur-Reply Decl. Ex. 29.) Written in May 1995 by Helen Burnham, Dey's Marketing Manager from 1990 to 1995,[8] this memo indicates that WAC prices were changed for no other reason than but to match those of a competitor's for purposes of Medicaid reimbursement. Clearly, Dey's WAC prices were, at least for a time, not real prices. Rather, like their AWPs, Dey's WAC prices were manipulated for competitive purposes. As such, Dey's argument that California could and should have used their more "accurate" WAC prices is farcical, inasmuch as it suggests that California could have avoided years of over-reimbursement on the basis of Dey's false AWPs by instead reimbursing instead on the basis of Dey's WAC prices, which were also false—i.e., by substituting one fabrication for another.

Dey also argues that "on multiple occasions in the late 1990s," California officials had considered using WAC prices instead of AWP. (Dey Reply Br. at 6.) Yet, other than the documents prepared by staff pharmacist Vic Walker—one of which Walker described as "a note to myself to help me organize what the task would be to make WAC happen" (Hanscom Sur-Reply Decl. Ex. 26 at 75:7-9)—there is no evidence that DHCS officials seriously considered WAC for reimbursement. On the contrary, although Walker did produce a number of spreadsheets purporting to incorporate WAC prices "as an option," and eventually provided the documents to his then-supervisor, Chief of Pharmacy Policy Len Terra, (*see* Hanscom Sur-Reply Decl. Ex. 26 at 67:18-68:14, 207:22-208:12) there is no evidence that Walker created the

[8] According to Dey CEO Charles Rice in his deposition on10-30-2001, Warrick's drugs had a higher WAC price than Dey's drugs. In Florida, a state which reimbursed on the basis of WAC prices, Dey was at a competitive disadvantage because customers preferred the higher reimbursement provided by Warrick's products. This memo changing Dey's WAC prices was in response thereto. (Hanscom Sur-Reply Decl. Ex. 30 at 119:22-159:19.)

documents for any official consideration.[9]

And once again, as previously noted, Walker clarified that the First DataBank prices to which he had mistakenly referred to as "WAC," were in fact "WHN" prices, which he understood to mean "net wholesale." (Hanscom Sur-Reply Decl. Ex. 26 at 87:22-88:15.) Moreover, that data had to be specially ordered (*id.* at 208:14-16), and "it took some work to get ahold of those numbers" (*id.* at 87:20-21). And even if DHCS had obtained the WAC prices from First DataBank, such data was not available for every drug. (Hanscom Sur-Reply Decl. Ex. 31 at 518:8-519:9.) The record simply does not support Dey's contentions that California's ability to use WAC prices constitute government knowledge.

C. Dey Cannot Rely Upon the OIG Reports with Regard to Its Government Knowledge Defense If It Did Not Itself Rely on Them.

In pressing its government knowledge defense, Dey neglects to note the critical fact that *no one* at Dey ever read or relied on the OIG reports. If *Dey* did not know what was contained in the OIG reports, then it follows that Dey, during the relevant period, could not possibly have concluded that California could be imputed to have had any understanding of a purportedly critical report of which Dey was at all times thoroughly ignorant. In order to invoke a government knowledge defense based on the OIG reports, *Dey must show that it then knew (i.e., during the relevant period), that California then understood from the OIG reports the facts of Dey's false AWPs, so that Dey could then knowingly rely on California's knowledge of the OIG reports to safely continue its fraudulent reporting of AWPs.* This argument fails because Dey never knew the contents of the OIG reports.

[9] *See, e.g.*, Hanscom Sur-Reply Decl. Ex. 26 at 66:21-67:6 (asked whether DCHS was aware of the availability of WAC pricing as a basis for reimbursement, Walker responded, "DHS is a very large organization with thousands of people. [¶] I was aware of it"); *id.* at 60:21-61:8 (deferring to Gorospe concerning the legislative budget process for changing pharmacy reimbursements); and Hanscom Sur-Reply Decl. Ex. 31 at 506:4-10, 507:19-508:7 (distinguishing Walker's proposal from the position of DHCS as a department).

When Dey CFO, Pam Marrs was deposed as a 30(b)(6) witness, she presented two binders full of OIG reports as exhibits. She testified that Dey's attorneys brought the reports to her attention, and she did not know if Bob Mozak had read the reports. (Hanscom Sur-Reply Decl. Ex. 32 at 517:19-519:21.) Ms. Marrs thought Russ Johnston was aware of the OIG reports. (*Id.* at 527:8-528:1.) Yet, Russ Johnston testified in his deposition that he had not read any government reports. (Hanscom Sur-Reply Decl. Ex. 33 at 26:21–27:2.) Ms. Marrs could not name anyone at Dey who was more knowledgeable than herself about the OIG reports. (Hanscom Sur-Reply Decl. Ex. 32 at 530:9-12.) And when Ms. Marrs was asked whether she had read any report in its entirety she replied, "probably not." (*Id.* at 530:17-20.) She did not know if anyone at Dey had read any of them. (*Id.* at 531:3-11.)

While Dey argues that California *could have used* the OIG reports, the issue is not what California could have read, or could have figured out; rather, the issue is whether California actually did use the OIG reports to learn about Dey's excessive spreads. As most of the reports concern Medicare and the Veterans Administration rather than Medicaid, it is understandable that Dey can point to no Medi-Cal personnel who read or relied on these reports to learn of Dey's pricing.

Furthermore, Dey did not contact Medi-Cal as a result of any OIG report. (CA SOAF Dey ¶ 1.)

Any reasonable reading of the OIG reports, and the DOJ AWPs, shows that the government was concerned about, and did not endorse, large spreads. This put Dey on notice that its reported AWPs were used to estimate provider acquisition costs.

D. The DOJ AWPs Never Succeeded.

Finally, Dey argues that the DOJ AWPs gave California access to true prices for "many" of the Dey Subject Drugs. To the extent that "many" includes 13 of the 28 NDCs California has

identified in the instant action, this is true. But after some consideration of the DOJ AWPS, California ultimately concluded that they were neither reliable nor workable for purposes of its reimbursement system—a conclusion that HCFA agreed with when, within nine months of their issuance, it withdrew the DOJ AWPs and, by written notice, specifically directed California not to use them. (CA Response SOF ¶ 38; Hanscom Decl. Ex. 24.[10]) Accordingly, even if California had decided to change its reimbursement formula to utilize these new AWPs, their use would have been short lived. When HCFA told California not to use the DOJ AWPs on November 17, 2000, the end date was immediate: "The *effective date* for this PM is upon receipt." (*Id.*) In addition, there was no method proposed for updating the prices, and First DataBank had no plans to do so. (*Id.*)

More fundamentally, Dey presents no evidence that it relied on either the OIG reports or the DOJ AWPs in deciding what AWPs it should publish. To the contrary, as set forth in Plaintiffs' motion for partial summary judgment, Dey set its AWPs based on those of comparable brand products. (Dey SOF ¶¶ 5, 6, 12.) Further, despite the information published by OIG and the DOJ AWPs, Dey continued to report fraudulent, inflated AWPs. Dey's continued submission of fraudulent, inflated AWPs when it was on notice of these governmental concerns regarding its prices does nothing to support Dey's defense; rather, it simply demonstrates its scienter. None of that evidence supports Dey's argument that the "government knowledge inference" rebuts the facts demonstrating that it acted with the scienter required by the CA FCA.

[10] Plaintiffs' Response to Defendants Dey, Inc. And Dey, L.P.'s Local Rule 56.1 Statement of Undisputed Material Facts In Support of Their Motion for Partial Summary Judgment (docket no. 6780); Declaration of Rita Hanscom in Support of Opposition (docket no. 6781).

III. CALIFORNIA'S RELEVANT EVIDENCE AS TO MEDI-CAL POLICY IS ADMISSIBLE.

Finally, Dey erroneously challenges California's use of testimony provided by Medi-Cal officials that it was never Medi-Cal's "policy to pay providers at rates that significantly exceeded their actual acquisition costs or to permit manufacturers to report AWPs that exceeded actual acquisition costs." (Dey Reply Br. at 9.) Dey argues that the testimony was obtained through leading questions, and that the responses were irrelevant. This is not so.

A "leading" question is one that asks the witness to acknowledge facts stated or suggested in the question. In effect, the questioner is testifying and simply asking the witness to affirm what the questioner has stated. Leading questions are permissible "as may be necessary to develop the witness' testimony." *See*, FED. R. EVID. 611(c); *United States v. Archdale*, 229 F.3d 861, 865–866 (9th Cir. 2000); *United States v. Smith*, 378 F.3d 754, 756, n.3 (8th Cir. 2004). The trial court has broad discretion to permit leading questions on direct where it is the most efficient manner of obtaining relevant evidence and the danger of improper suggestion is minimal. *United States v. Hall*, 165 F3d 1095, 1117 (7th Cir. 1999); *United States v. Olivo*, 69 F.3d 1057, 1065 (10th Cir. 1995); *see Borge v. Our Lady of the Sea Corp*., 935 F.2d 436, 442 (1st Cir. 1991) ("trial judge has wide latitude to regulate the conduct of trial").

In the instant case, in questioning both Mr. Rosenstein and Dr. Gorospe, while some of Mr. Paul's questions could have been answered "yes" or "no," there is no indication that Mr. Paul's questions necessarily suggested either answer. Indeed, upon review of the questions and, more particularly, Mr. Rosenstein's and Dr. Gorospe's responses, it is inconceivable that Mr. Paul's questions could be deemed as directing either deponent's testimony, or that he was testifying in their place. While Dey may not like the deponents' responses, their detailed and explicit testimony is clearly their own.

Furthermore, both Dr. Gorospe and Mr. Rosenstein were DHCS's designated 30(b)(6) deponents for a number of issues in this action. This, of course, means that both deponents could very well have submitted the referenced testimony via an affidavit, which not only would have suggested their answers, but would actually be written by Plaintiffs' counsel. Accordingly, even to the extent that the Court finds that either deponent's referenced testimony was in response to a leading question, Defendants are hard pressed to indicate how they might have been prejudiced by it, given that both deponents could have just as easily submitted the same, perhaps even more comprehensive, testimony by way of a signed declaration.

The testimony is also relevant. The crux of Dey's "government knowledge" argument is that it advised California officials of its price reporting practices, and that Medi-Cal officials approved or acquiesced in those practices. The government knowledge cases that Dey cites are replete with testimony concerning the policies of government agencies and the understanding of responsible government officials. Dey cannot have it both ways. It cannot mount a "government knowledge" defense, but declare that the responsible government officials are precluded from testifying as to their respective agency's policies and practices. Dey's position in this regard reveals the impossible nature of its government knowledge argument.

CONCLUSION

For the above reasons, Plaintiffs respectfully request this Court to deny Dey's motion for partial summary judgment.

Dated: January 29, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on January 29, 2010, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Rita Hanscom
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